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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/091,359	03/04/2002	Bernd Roesicke	RDID01033US	7290
23690	7590	03/07/2005	EXAMINER	
Roche Diagnostics Corporation 9115 Hague Road PO Box 50457 Indianapolis, IN 46250-0457			ALEXANDER, LYLE	
			ART UNIT	PAPER NUMBER
			1743	

DATE MAILED: 03/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/091,359

Applicant(s)

ROESICKE ET AL.

Examiner

Lyle A Alexander

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 December 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 19-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 19-40 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

See the appropriate paragraph of the 7/6/04 Office action.

Claim 19 remains unclear where the two openings are because the openings are never defined in the claim. The structure reflected by the first and second positions is not clear. Furthermore, the relationship between the dosing chamber, dosing element and the other chambers is not clearly set forth.

***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 19-40 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Warden et al.

See the appropriate paragraph of the 7/6/04 paper.

***Response to Arguments***

Applicant's arguments filed 12/30/04 have been fully considered but they are not persuasive.

Applicants traverse the 35 USC 112-second paragraph rejections on the basis the Office has not read the claims in light of the specification. Applicants have helpfully

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described the claims in light of the specification. However, the claims still lack basic elements such as descriptions of the two openings, the first and second positions, etc.

Amendments reciting the structures described in the remarks may further the prosecution. Exemplary is description of a spherical dosing element chamber containing a dosage capillary having a length that is approximately the same as the diameter of the dosing element chamber and a first and a second opening at opposite ends of the dosing chamber such that the dosing element when appropriately oriented will create a fluid path from the first opening through the capillary dosing element to the second opening and the dosing element chamber having a third opening the dosing element may aligned with that is not in fluid communication with the first or second position and where the dosing element will fill with the sample. Such amendments were inspired by Applicants description of the invention on pages 4-5 of the 12/30/04 remarks. These are just suggestions and Applicants may be able to convey the same effect with only minor changes of the pending claims. Amendments submitted after final will be scrutinized if new issues are raised that would further consideration and may not be entered.

Applicants traverse the 35 USC 102(b) rejections over Warden et al. on the basis this reference fails to teach the claimed movable dosage element. In light of the above 35 USC 112 issues, it is not clear how the dosage element is integrated with the device and the rejection over Warden et al. is proper.

Upon further Appeal and clarification of the 35 USC 112 second paragraph issues, the Office may make a 35 USC 103 rejection of Warden et al. in view of

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Uffenheimer (USP 5,558,838). Uffenheimer teaches a similar device that samples blood from a sample tube. Uffenheimer teaches in column 4 lines 27+ a shear valve (36) that is rotated to collect a predetermined amount of sample. The shear valve is advantageous because it permits saving a portion of the sample for other testing. It would have been within the skill of the art to modify Warden et al. in view of Uffenheimer and use a shear valve to gain the above advantages.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Stamm and Hauck teach rotary valves for sample acquisition are known in the art.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lyle A Alexander whose telephone number is 571-272-1254. The examiner can normally be reached on Monday, Wednesday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lyle A Alexander  
Primary Examiner  
Art Unit 1743



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